K092464
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## Appendix C 510(k) Summary

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|---|---|
| **Applicant:** | Spineology Inc.<br>7200 Hudson Blvd North<br>Suite 205<br>St Paul, MN 55128-7055<br>Phone: 651-256-8500<br>Fax: 651-256-8505 |
| **Contact Person:** | Karen Roche |
| **Date Prepared:** | August 3, 2009 |
| **Trade Name:** | Spineology Facet Screw System |
| **Product Classification and Code:** | Unclassified, Product Code MRW |
| **Predicate Device(s):** | **K071420** Chameleon™ Fixation System (SpineFrontier™, Inc.)<br>**K073515** TranS1 Facet Screws (TranS1,® Inc.) |
| **Device Description:** | The Spineology Facet Screw System is designed to provide bilateral transfacet fixation of the lumbar facet joints. The cannulated screw is available partially or fully threaded in a range of lengths and is made from medical grade titanium alloy that complies with ASTM F-136. |
| **Intended Use:** | The Spineology Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation.<br><br>The device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: Spondylolisthesis, Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability. |
| **Summary of Technological Characteristics:** | The device is shown to be substantially equivalent to the intended use, materials, configuration, and performance characteristics of the predicate products. |
| **Conclusion:** | The information submitted in this premarket notification supports a determination that the Spineology Facet Screw System is substantially equivalent in technological characteristics and intended use to the predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Spineology, Inc.
% Ms. Karen Roche, Vice President
Operations and Technology
7200 Hudson Boulevard, N., Suite 205
Saint Paul, Minnesota 55128-7055

Re: K092464
Trade/Device Name: Spineology Facet Screw System
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: MRW
Dated: August 3, 2009
Received: August 11, 2009

Dear Ms. Roche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Appendix D Indications for Use Form

**Device Name:** Spineology Facet Screw System

**Indications for Use:**

The Spineology Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation.

The device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: Spondylolisthesis, Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092464